

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: NIKOLAI. AFANASENKO ET AL. (PCT)

SERIAL NO.: 08/646,213

GROUP: 3302

FILED May 7, 1996

EXAMINER: J. CLARK

TITLE: DEVICE FOR TREATMENT OF PATIENTS WITH DISTURBED
POSTURE AND MOTOR ACTIVITY

DECLARATION UNDER RULE 132

ATTN: BOX FEE AMENDMENT
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, OLEG VIKTOROVICH BOGDANOV, declare that since 1992, I have been Director of the Children's Rehabilitation Center "Vozvrashchenie", Professor, Dr. Sc. (Med.); and that the following clinical tests (EXHIBIT G) were conducted under my supervision:

EXHIBIT G

Clinical Efficacy of Application of the Therapeutic Loading Suits MK-92 "Adeli" in Complex Rehabilitation of ICP Patients

A treatment course with the MK-92 "Adeli" therapeutic suit was given from January 15, 1996 to January 15, 1997 to 15 patients with the various forms of ICP (of whom five were given a repeated course) aged from 4 to 17.

Distribution of the ICP patients according to the degree of severity of disease is present in Table 1 below.

Table 1

Distribution of patients according ICP forms and the degree of severity of the disease

| Degree of severity (according to clinical scale) | ICP forms | | |
|---|-----------|-------|--------------|
| | Spastic | Mixed | Hyperkinetic |
| Severe | 2 | | |
| Moderate-severity | | 1 | |
| | 2 | | 1 |
| Moderate | 6 | - | 1 |
| Mild | 4 | 1 | 1 |
| Total | 14 | 2 | 3 |

All the patients admitted for a treatment course with the "Adeli" suit passed a medical examination by a neuropathologist and an orthopedist, as well as were tested for the condition of themotor functions according to clinical point scales both before and after the treatment course besides, the patients were subjected to electrophysiological examinations (electroencephalography, electromyography, radioencephalography, myogenic tonus) and psychological examination (assessment of patients' psychoemotional status and intellectual development. It is on the basis of the results of such a primary examination that a treatment scheme was drawn up for each patient, taking consideration of the ICP form, a leading pathological link, and the degree of severity of the affection; the scheme included a preparative and a main stages (see Table 2 below)

Table 2

Clinical Scale N 2

- 1) Items of clinical scale
- 2) Pretreatment status, % of norm
- 3) Maximum possible improvement, % of norm
- 4) Actual improvement, % of norm
- 5) Percentage of functional reserve utilization
- 6) Turn from prone to supine position
- 7) Turn from supine to prone position
- 8) Crawling on the belly
- 9) Sitting with the legs stretched out
- 10) Sitting on a couch with legs dangling

- 11) Sitting up from prone position through side sitting position
- 12) Sitting up from supine position through side sitting position
- 13) Symmetrical sitting up from supine position
- 14) Going down on all fours
- 15) Crawling on all fours
- 16) Kneeling
- 17) Walking on knees
- 18) Standing up from kneeling position
- 19) Ability to assume standing posture
- 20) Standing on one leg
- 21) Walking with a support
- 22) Spontaneous walking
- 23) Going upstairs
- 24) Going downstairs

According to the results of testing patients' motor functions performed preparatory to the treatment course, an average coefficient was calculated for each item of the clinical scale in percent of norm (assuming as 100% was the state of a given function in a sound child of the corresponding age), as well as

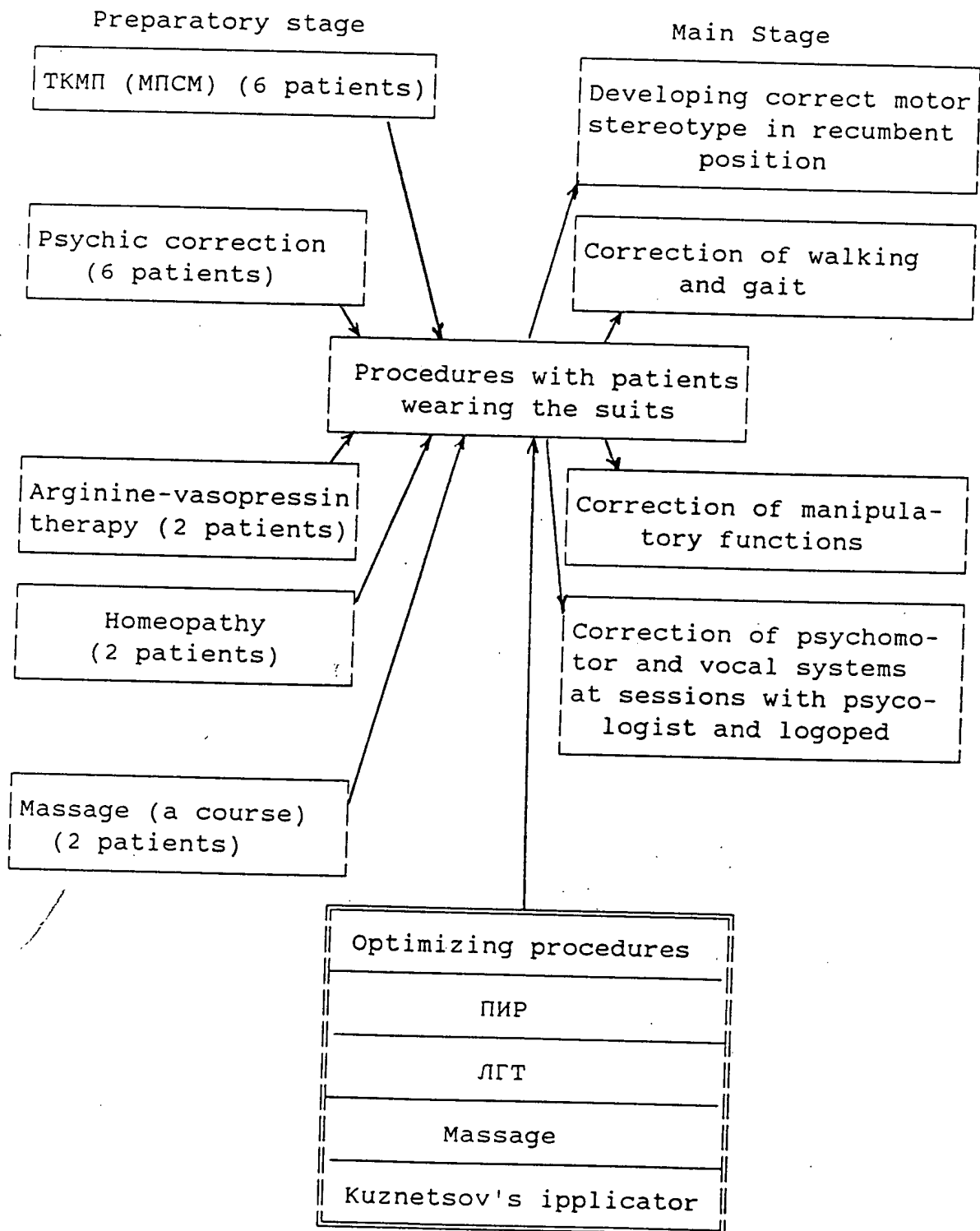
the maximum possible improvement (functional reserve) . In post-treatment examination there was assessed an actual improvement of each item of the clinical scale and a degree of utilization of the functional reserve (that is, the percent ratio between an actual improvement and a maximum possible one. The results are present in Table 3.

Table 3

Clinical scale N 1

- 1) Items of clinical scale
- 2) Pretreatment status, % of norm
- 3) Maximum possible improvement, % of norm
- 4) Actual improvement, % of norm
- 5) Percentage of functional reserve utilization
- 6) ~~Kinesthesia~~ and proprioception
- 7) Extent of motion
- 8) Hyperkinetic or cerebellar syndrome
- 9) Supporting ability
- 10) Social and everyday life habits

Diagram of rehabilitation measures involving
the use of therapeutic loading suits ЛК-92 "Adeli"



Changes in patients' motor functions after a treatment course
with the therapeutic loading suits π -92 "Adeli"

Notation:

I- Posttreatment changes in clinical point scale indices The whole
circle denotes a 100% state of a given characteristic in sound
child of a corresponding age Circle sectors:

A Pretreatment state of the characteristic B -Posttreatment
improvement C - Posttreatment degree of affection of the
characteristic

II- Utilization of the functional reserve

The whole circle denotes a 100% maximum possible improvement (up to
norm) (the sum of sectors B and C in graph I)

~~Circle~~ sectors:

A -Improvement in a given characteristic per treatment course
B -Unutilized reserve

Kinesthesia and proprioception

I

II

EXTENT OF MOTION

I

II

Presence of hyperkinetic or cerebellar syndrome

I

II

Supporting ability

I

II

Social and everyday life habits

I

II

Improvement in manipulatory functions during

procedures with the therapeutic

loading suits ПК-92 "Adeli"

A - performing manipulations with more affected hand

B - same with less affected hand

I - Rate manipulations with domestic test-pieces on the stand for
developing: social and everyday life habits. X-axis - seconds;

Y-axis - sessions with the suits put on

II - Number of errors in passing a probe along a labyrinth X-axis -

number of errors; Y-axis - sessions with the suits put on

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true' and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 27.07.98

Name: 
OLEG VIKTOROVICH BOGDANOV

Title: Director of the Children's Rehabilitation Center
"Vozvraschenie", Professor, Dr. Sc. (Med.).

Diagram of rehabilitation measures
involving the use of therapeutic
loading suits JK-92 "Adeli"

- 1) Preparatory stage
- 2) Main stage
- 3) ТКМП (МПСМ) ? (6 patients)
- 4) Psychic correction (6 patients)
- 5) Arginine-vasopressin therapy (2 patients)
- 6) Homeopathy (2 patients)
- 7) Massage (a course) (2 patients)
- 8) Procedures with patients wearing the suits
- 9) Optimizing procedures
- 10) ПИР (?)
- 11) ЛГТ (?)
- 12) Massage
- 13) Kuznetsov's applicators
- 14) Developing correct motor stereotype in recumbent position
- 15) Correction of walking and gait
- 16) Correction of manipulatory functions
- 17) Correction of psychomotor and vocal systems at sessions with psychologist and logoped

CONTRACT

on conducting trials of therapeutic suit
"Adeli" with a view to determining a
possibility of using it as a sports exerciser

Moscow

October 05, 1995



The joint-stock company "AYURVEDA" hereinafter called "Firm", in the person of its Director-General FIKSK, revgeni Adievich acting on the grounds of the Charter of said company, and the All-Russia Track and Field Athletics Federation hereinafter called "Federation", in the person of President of the Federation BALAKHNICHEV, Valentin Vasilievich acting on the grounds of the Charter of said Federation, have this day entered into the present contract as provided hereinbelow.

1. SUBJECT MATTER OF CONTRACT

Trials of the device "ADELI" for as a sports exerciser.

2. LEGAL DUTIES OF THE PARTIES

2.1. The Firm undertakes:

2.1.1. To furnish the Federation with two sets of the device (suits) "ADELI" for a period of trials. The suits shall be returned to the Firm after completing the trials.

2.1.2. To perform a general coordination in carrying out joint work, to integrate research materials and reports on the results of trials via the Research and Advisory Council (Barer A.S., Semenova K.A.).

2.2. Federation undertakes:

2.2. To provide material facilities for trials of the device "ADELI" and perform trials with participating the following specialists:

Group Manager - Korostelev A.V.

2.2.2. To make a scientific analysis of the results obtained and present to Firm, in keeping with an approved schedule of work, reports on work done.

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JĘZYKA ANGIELSKIEGO
mgr Jan Konieczny
ul. Oskara Lange 28D/4, tel. 43-62-50
75-433 KOSZALIN

Jan Konieczny



- 2 -

3. TERM OF SUBMITTING WORK

3.1. Contents and terms of execution of main stages of work are specified in the schedule of work.

5. WORK ACCEPTANCE PROCEDURE

5.1. Upon completion of the whole work Federation shall present to Firm a report approved by the Research and Advisory Council.

LEGAL ADDRESSES OF THE PARTIES:

Federation: 8, Luzhnetskaya nab., 119871 Moscow, Russian Federation.

Firm: 5/10, Litovski bulvar, 275, 117593 Moscow, Russian Federation.

Schedule of Work

Conducting trials October 6, 1995 to January 15, 1996

Report on clinical trials January 30, 1996

REPERTORY No: 62/98

This will certify that the above is a true and correct translation of respective Russian original.

Jan Konieczny
Jan Konieczny, MA, Sworn-in-interpreter of English
Koszalin: 27th of May 1998



Collected fee: zł.18.00gr

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on clinical trials of the therapeutic suit "Adeli"
aimed at determining a possibility of its application
as a sports exerciser

Moscow

January 30, 1996



On the grounds of a contract concluded with the Joint-Stock Company "Ayurveda", the Track and Field Athletics Federation performed, in a period from October 6, 1995 to January 15, 1996, trials of the therapeutic suit "Adeli" aimed at determining whether said suit may be applied as a sports exerciser. Trials were performed for a period of three months on a group of track and field athletes fourteen in number by using said suit in the course of sports trainings.

The trials have revealed as follows:

1. The construction of knee caps fails to hold the tie-members in a preset direction.
2. The shoe attachment arrangement available does not provide an adequate fixing.
3. Putting-on the suit takes substantially much time.

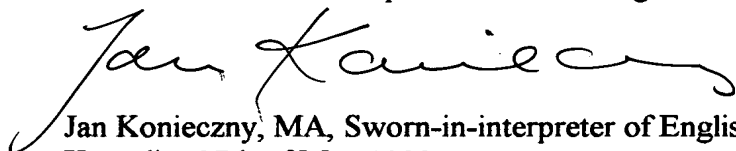
In the course of trials the Coach Council has come to a conclusion that the suit "Adeli" cannot be used as a sports exerciser.

On behalf of Federation Balakhnichen V.V., President

On behalf of Joint-Stock Company "Ayurveda" Firer Ye.A.,
Director-General

REPERTORY No: 61/98

This will certify that the above is a true and correct translation of respective Russian original.


Jan Konieczny, MA, Sworn-in-interpreter of English
Koszalin: 27th of May 1998



Collected fee: zł.54.00gr

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ДОГОВОР
НА ПРОВЕДЕНИЕ ИСПЫТАНИЙ ЛЕЧЕБНОГО КОСТЮМА "АДЕЛИ"
С ЦЕЛЬЮ ОПРЕДЕЛЕНИЯ ВОЗМОЖНОСТИ ИСПОЛЬЗОВАНИЯ ЕГО В
КАЧЕСТВЕ СПОРТИВНОГО ТРЕНАЖЁРА



г.Москва

05.10.95

Акционерное общество "АЮРВЕДА", именуемое в дальнейшем "Фирма", в лице Генерального директора Фирера Евгения Адиевича, действующего на основании Устава, с одной стороны, и Всероссийская федерация лёгкой атлетики, именуемая в дальнейшем "Федерация" в лице Президента федерации Балахничёва Валентина Васильевича, действующего на основании Устава, с другой стороны заключили настоящий договор о нижеследующем.

1. ПРЕДМЕТ ДОГОВОРА.

Проведение испытаний устройства "АДЕЛИ" для применения его в качестве спортивного тренажёра.

2. ОБЯЗАННОСТИ СТОРОН.

2.1. Фирма обязуется:

2.1.1. Предоставить Федерации устройства "АДЕЛИ" в количестве двух комплектов на время проведения испытаний. После проведения испытаний костюмы возвращаются фирме.

2.1.2. Осуществлять общую координацию проведения совместной работы, объединять научные материалы и отчеты по результатам работы через научно-консультативный совет (Барер А.С., Семенова К.А.)

2.2. Федерация обязуется:

2.2.1. Предоставить базу для проведения испытаний устройства "АДЕЛИ" и провести испытания специалистами в составе:

Руководитель группы Коростелёв АВ.

2.2.2. Провести научный анализ полученных результатов и представление "Фирме", по утвержденному календарному плану отчетов о проделанной работе.

3. СРОК СДАЧИ РАБОТ.

3.1. Содержание и сроки выполнения основных этапов определяются Календарным планом.

5. ПОРЯДОК СДАЧИ ПРИЁМКИ РАБОТ.

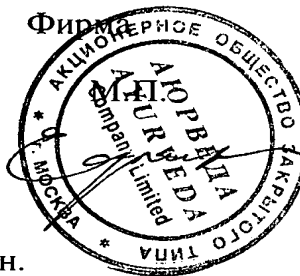
5.1. При завершении работ в целом Федерация представляет Фирме отчет утверждённый научно консультативным советом.



АДРЕСА СТОРОН:

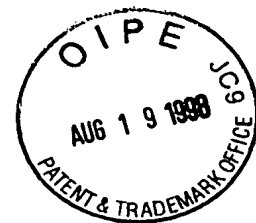
Федерация: 119871, г. Москва. Лужнецкая наб. 8.

Фирма: 117593 г. Москва Литовский бульвар 5/10 (275)



Календарный план.

| | |
|--------------------------|------------------------|
| Проведение испытаний | с 06.10.95 по 15.01.96 |
| Отчёт о клин. испытаниях | 30.01.96 |



Протокол
проведения испытаний лечебного костюма «Адели»
с целью определения возможности использования его
в качестве спортивного тренажёра.

Г. Москва

30.01.96.

На основании договора с акционерным обществом «Аюрведа» с 06.10.95. по 15.01.96 Федерацией лёгкой атлетики были проведены испытания лечебного костюма «Адели» с целью выявления возможности использования его в качестве спортивного тренажёра. В течении трёх месяцев испытания проводились на группе легкоатлетов из четырнадцати человек, путём использования костюма в процессе проведения тренировок.

Испытания выявили:

1. Конструкция надколенников не позволяет фиксировать тяги в заданном направлении.
2. Существующее устройство крепления обуви не предусматривает достаточной фиксации.
3. Одевание костюма требует существенных временных затрат.

В процессе проведения тестирования тренерский совет пришёл к заключению о невозможности использования представленного костюма «Адели» в качестве спортивного тренажёра.

От Федерации:

Президент федерации

Балахничёва В.В.

От АОЗТ «Аюрведа»:

Директор

Фирер Е.А.